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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,492

11/20/2003

Christopher C. Toly

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04/04/2008

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EXAMINER

MUSSELMAN, TIMOTHY A

ART UNIT

PAPER NUMBER

3714

MAIL DATE

DELIVERY MODE

04/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/718,492	Applicant(s) TOLY, CHRISTOPHER C.	
	Examiner TIMOTHY MUSSELMAN	Art Unit 3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-11,14,15,17-41,43-45,48-61,74,76-81 and 88-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11,14,15,17-41,43-45,48-61,74,76-81 and 88-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/07,2/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

In response to applicant's submission dated 12/12/2007, claims 1, 2, 4-11, 14, 15, 17-41, 43-45, 48-61, 74, 76-81 and 88-10 are currently pending. Claims 4-6, 11-14, 17-19, and 36 have been withdrawn from consideration as a non-elected species subject to rejoinder upon allowance of a generic claim. Claims 42, 46, and 62-73 have been cancelled as being directed to a non-elected invention. Claims 13, 42, 46-47, and 62-73 have been previously cancelled. Claims 3, 12, 16, 75, and 82-87 are cancelled herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the relevant portion of 35 U.S.C. 102 that forms the basis for the rejections made in this section of the office action;

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

Claims 2, 7, 9, 15, 20-28, 35, 37, 45, 48-50, 53-61, 74, 76-77, 88-90, and 97-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (US 4,134,218).

Regarding claims 2, 24, 57-58, 60, and 74, Adams discloses a simulated tissue structure which comprises a plurality of conductive polymer sensor strips embedded within the structure in layers, wherein the strips also act as a functioning portion of the skin, wherein the sensor elements provide electrical pressure data pertaining to a procedure being performed on the simulated structure. See col. 7: 1-60. With particular respect to the claims 57-58 and 60, the equivalent structure anticipates a product-by-process claim. See MPEP 2113, which provides more detail and several case citations.

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Regarding claims 48 and 55, Adams further discloses wherein the sensors detect a change in pressure to the anatomical structure. See col. 8: 36-44.

Regarding claims 7, 20, it is disclosed in col. 8: 36-44 wherein the user palpates (i.e. touches) the system to produce a signal.

Regarding claims 9, Adams further discloses wherein the pressure sensing system acts as a resistance sensitive switch. See col. 7: 45-50.

Regarding claim 45, 53-54, 88-89, and 97, Adams further discloses wherein applied pressure to the mechanism causes the resistance to drop to as low as 0.1 ohms (i.e. effectively eliminating the non-conductive gap and closing a conductive path thus electrically coupling the conductive segments). See col. 7: 45-50.

Regarding claim 15, Adams discloses wherein the pressure sensitive elements provide signals for either the open circuit state (no-pressure), or the closed circuit state (max pressure), and transitions there between. See col. 10: 8-31.

Regarding claims 21-23, 31, 49-50, 61, and 76-77, Adams further discloses an indicator coupled to the evaluation circuit that provides a light (computer screen) indicating feedback, and a meter (applied pressure displayed on the screen). See col. 11: 4-47.

Regarding claim 25, Adams further discloses wherein the simulated tissue structure comprises elastomeric membranous and sub membranous layers. See col. 4: 16-46 and col. 7: 5-10.

Regarding claims 26-28, 37, 56, and 59, Adams discloses wherein the evaluation circuit is implemented in three dimensions. See col. 10: 8-31. Note that the grid area as well as the applied pressure together detects a 3D location and evaluation mechanism.

Regarding claim 35 and 36, Adams further discloses wherein the structure is an organ. See col. 1: 6-16. The sensors are located on the periphery of the organ as described in fig. 2, label 59.

Regarding claim 90, Adams further discloses wherein the system provides data pertaining to correct and incorrect performance of a procedure. See col. 11: 32-47.

Regarding claim 98, Adams discloses all of the features described above in reference to claim 2, and further discloses in col. 11: 35-40 that the system can store performance data (which can be viewed or not viewed by anybody).

Claims 91 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Nicholls et al. (US 2003/0068606).

Regarding claims 91 and 95, Nicholls discloses a simulated physiological tissue structure with an outer surface and comprising a conductive elastomer evaluation circuit comprising a grid of multiple conductive layers parallel to the outer surface configured to provide signals for feedback regarding the performance of a simulated medical procedure pertaining to positional information of an instrument. See paragraphs 13 and 14.

Claim Rejections - 35 USC § 103

The following is a quotation of the relevant portion of 35 U.S.C. 103 that forms the basis for the rejections made in this section of the office action;

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Claims 1, 38-41, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton et al. (US 4,872,841) in view of Adams et al. (US 4,134,218).

Regarding claims 1, Hamilton discloses a medical training system which requires proper placement of elements in order to open particular sensory circuits, and close others. See col. 2: 8-25. Hamilton does not teach of using elastomer circuits configured as the structure, but this is known in the art of medical simulations systems as taught by Adams. It would have been obvious to one of ordinary skill in the art at the time of the invention to seek to improve the device of Hamilton by incorporating the broad concept of elastomer based circuits as taught by Adams, because this would be updating the system of Hamilton with current technology established in the art.

Regarding claims 38-41, Hamilton further discloses wherein the system simulates a joint between bones (vertebrae in a spinal column), and the sensors are configured to detect proper alignment which indicates proper performance of a procedure. See col. 1: 30-50.

Regarding claim 96, Hamilton discloses the opening of circuits as described with regard to claim 1 above, and further discloses an exterior portion and a target portion. See col. 3: 3-34. The use of the elastomer would have been obvious in view of Adams as described above with respect to claim 1.

Claims 8,10, 51-52, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US 4,134,218) in view of D'Antonio et al. (US 5,589,639).

Regarding claims 8, 10, 51-52, and 99, Adams discloses all of the features wherein the system includes a conductive elastomer evaluation circuit and wherein the evaluation circuit effectively acts as a switch between a closed and open position. See the rejection of claims 2 and 9 above. Adams does not teach of using capacitance based sensors and switches. However, D'Antonio teaches of a device for use in medical procedures that is directed towards solving the problem of sensing parameter changes in an environment and producing a corresponding signal. See col. 5: 21-27, wherein D'Antonio teaches of a Schmitt trigger switching device that is dependant upon a resistive, capacitive, or inductive signal from the respective sensors. D'Antonio further discloses an inductor to induce a signal to the sensing circuit. See col. 4: 45-50. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Adams to include various sensor and switch types known in the data acquisition art as taught by D'Antonio, because this would just be the use of alternate equivalent sensory schemes currently known in the art.

Claims 92-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholls (US 2003/0068606) in view of Pugh (US 6,428,323).

Regarding claims 92-94, Nicholls discloses that positional feedback regarding the instrument is available as described above with regard to claim 91, but does not teach wherein the feedback is a series of lights indicative of how close the instrument is to the desired position. However, Pugh teaches of a palpation simulator that discloses this broad concept. See col. 7: 41-67. Note that as the student applies pressure to the proper area of the simulator, the light bar rises, until finally the proper task is checked off. It would have been obvious to one of ordinary skill in the art to combine this feature with the system of Nicholls, because it would be the use of a known positional evaluation mechanism in a system that detects position. That is to say the concept as broadly taught by Pugh applied to additional position tracking systems would not involve an inventive step. The arrangement of the lights in a bulls eye configuration is an arbitrary design consideration which does not functionally distinguish over the system of Nicholls/Pugh.

Claims 29-30, 32-34, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US 4,134,218) in view of of Eggert (5,853,292).

Regarding claims 29-30, Adams discloses as described above a system that utilizes conductive elastomer in a medical simulation system in a fashion that meets all of the limitations of claim 2. However, Adams does not disclose any fluid channels, with or without sensory elements in the walls of the fluid channels. However, Eggert teaches of the medical simulation concept of sensors in the walls of simulated arteries in col. in col. 5: 18-36. It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the circulatory system wall detection of Eggert with the elastomer evaluation circuits of Adams, because this would have been a combination of concepts known in the art that would not work differently in combination then they did in isolation.

Regarding claims 32-33 and 78, Adams discloses as described above a system that utilizes conductive elastomer in a medical simulation system including as an evaluation circuit in a fashion that meets all of the limitations of claim 2. Adams fails to teach of a physiological control element being coupled to the evaluation circuit so that the processor uses the evaluation circuit to control the physiological control element, and wherein the control element includes a servo and a pump. However, Eggert teaches of these features in col. 4: 45-60. It would have been obvious to one of ordinary skill in the art at the time of the invention to include these mechanical feedback systems in the invention of Adams because this would have been a combination of concepts known in the art that would not work differently in combination then they did in isolation.

Regarding claim 34, Adams discloses wherein the sensory circuits are distributed in a series of branches extending throughout the system. See col. 10: 8-31.

Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US 4,134,218) in view of Nicholls et al. (US 2003/0068606).

Regarding claims 43 and 44, Adams discloses the use of a simulated tissue structure comprising a simulated organ as described in above with respect to claim 2. Adams does not disclose wherein the structure is enclosed in a case with predefined openings for access, and wherein the organ structure comprises replaceable incisable elements. However, these concepts are all well known in the art of medical simulations, and are disclosed by Nicholls in at least paragraph 10. The combination of these elements known in the art would have been obvious to one of ordinary skill in the art at the time of the invention, because the combination would be the combination of known concepts in the art and no unexpected results would ensue.

Claims 79-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton et al. (US 4,872,841) in view of Adams et al. (US 4,134,218) and also in view of Beach et al. (US 6,857,878).

Regarding claims 79-81, Hamilton/Adams disclose a bone structure with elastomer based sensors and a controllers to store student performance data to determine a rate of student learning (claim 81). See col. 9: 20-43. However, there is no explicit teaching wherein a score is determined to ascertain a rate of learning, or wherein the score is compared to previous procedures. However, these concepts are old and well known in the art of medical simulations. For example, Beach discloses a medical trainer that includes these concepts. See col. 11: 66-67, and col. 12: 43-48. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the scoring aspects of Beach into the system of Hamilton/Adams, so as to improve the system in a manner known in the art by allowing users of the simulation to monitor their performance and improvements therein.

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Claim 100 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (US 4,134,218) in view of of Damadian (US 6,544,041).

Regarding claim 100, Adams discloses a structure comprising a conductive elastomer based evaluation circuit which provides feedback to the user as described in claim 2 above. Adams does not disclose the use of a tool which induces a current into the evaluation circuit without contact. However, this concept is established in the art. For example, Damadian discloses a medical training apparatus that makes use of contactless sensory elements in which current is magnetically induced in sensory elements. See col. 6: 23-35. It would have been obvious to one of ordinary skill in the art at the time of the invention to include various sensory schemes known in the art with the elastomer sensory elements of Adams, because it would only be a combination of existing concepts and there would be no unexpected results ensuing from such a combination.

Response to Arguments

Applicants arguments dated 12/12/2007 have been fully considered, but are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY MUSSELMAN whose telephone number is (571)272-1814. The examiner can normally be reached on Mon-Thu 6:00AM - 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. M./
Acting Examiner of Art Unit 3714

/Robert E Pezzuto/
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TM

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